REMARKS

Claims 44-46 and 49-51 are currently pending in the application.

Applicants note that the Office Action Summary does not indicate which claims stand rejected, but merely indicates that claims 44-46 and 49-51 are currently pending in the application. In the Detailed Action, the Patent Office indicates that the finality of the previous Office Action has been withdrawn and that claims 44-46 and 49-51 stand rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. U.S. Patent No. 5,942,606. The Office Action contains no indications regarding other rejections made in the previous Office Action and arguments presented in the previous response. In view of this, Applicants have included their earlier presented arguments where pertinent.

Claims Rejections - 35 U.S.C. §112, first paragraph

The previous Office Action (Paper 20) rejected claims 39-43, 50, and 51 under 35 U.S.C. §112, first paragraph, for alleged lack of enablement and for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention. Claims 39 - 43 were previously cancelled without prejudice and claim 50 was amended to depend from claim 44 in the last response. Claim 51 depends from Claim 50. Rejections which are not repeated are presumed withdrawn (Paperless Accounting Inc. v. Bay Area Rapid Transit Sys. 804 F 2d 659, 231 USPQ 649 (Fed. Cir. 1986))

Since there are no claims currently pending in this application which stand rejected under this provision, this rejection is moot. Applicants assume that this rejection is withdrawn.

Claim Rejections - 35 USC §102

Claims 44-46, and 49-51 stand rejected under 35 USC §102(e) "as being anticipated by Lal et al. 5,942,606." Claim 51 is added to the rejection because it was noted that Lal teaches an epitope tagged fusion polypeptide, col. 12, lines 38-44.

The present application is entitled to the priority date of October 24, 1997, which precedes, by one month, the earliest priority date of Lal et al. (November 24, 1997). Accordingly, Lal et al. is not prior art against the present application, and this rejection

should be withdrawn. Withdrawal of this rejection and allowance of this application is respectfully requested.

The Examiner acknowledges that applicants have claimed priority to U.S. Provisional Patent Application No. 60/062,816 filed on October 24, 1997. Applicants maintain that the effective filing date of this application is October 24, 1997. Applicants submit that the priority document disclosure does provide sufficient information to enable one skilled in the art to practice the claimed invention. No pending claims currently stand rejected for lack of enablement. Accordingly, Applicants maintain that they are entitled to the priority date, thereby eliminating Lal et al. as prior art.

The Office Action states that Applicants cannot rely upon the similarity in structure to CAR to infer function and usefulness as a viral receptor. The art cited by the Examiner allegedly teaches that minor changes in structure can have major effects upon function in a virus receptor protein.

The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what is already known, the specification teaches those in the art enough that they can make and use the invention without "undue experimentation"" Amgen Inc. v. Hoechst Roussel, Inc. 65 USPQ 2d 1385-1421, 1400 (Fed Cir 2003) citing Genentech, Inc. v. Novo Nordisk, A/S 42 USPQ 2d 1001, 1004 (Fed Cir. 1997). "That some experimentation is necessary does not constitute a lack of enablement" Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. 18 USPQ 2d 1016, 1026.

The present application, and its earliest priority application 60/062,826 filed on October 24, 1997, provide the nucleic acid and amino acid sequence of the PRO246 polypeptide and indicate that this amino acid sequence shares significant homology to the human Coxsackie-adenovirus receptor. The disclosure further states that a portion of the PRO246 polypeptide has significant homology with the human cell surface protein HCAR. It was known in the art at the earliest priority date of the present application that HCAR is a human cellular receptor for the group B Cocksackie-viruses (CVB), and human subgroup C adenoviruses (Ad2 and Ad5) (see Tomko *et al., Proc. Natl. Acad. Sci. USA* 94:3352-3356 (April 1997), a copy of which was previously submitted). Considering its significant homology to the human Coxsackie adenovirus receptor,

Applicants further suggest the PRO246 polypeptide to be a novel cell surface virus receptor. The specification, at, for example, pages 118-199 and Examples 53-55, provides methods of transforming prokaryotic and eukaryotic cells with the PRO genes and methods of expressing the PRO gene in prokaryotic or eukaryotic cells

The Examiner indicates that she fails to see where Tomko provides evidence of general knowledge in the art to discover a virus bound to the hypothetical receptor. Further, the priority document allegedly does not identify any specific virus which interacts with the viral receptor, requiring those skilled in the art to perform experimentation to discover a specific use for this protein.

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. In re Wands 858 F.2d 731, 737.

Applicants note that Tomko et al. provides a general virus assay on page 3352. Tomko provides a method for transfecting NIH3T3 cells with a plasmid expressing the receptor (page 3352). Tomko et al. provides a virus assay to be conducted with different viruses on the transformed cells (page 3352). Clearly such assays could be routinely used at the earliest priority date of the present application to identify the specific viruses that use the PRO246 polypeptide as their receptor.

The Office Action states that the regions most similar to the virus receptor CAR are found in a nonessential region of CAR and the region of CAR which functions by interacting with a virus shows little or no similarity to applicant's sequence. However, the Patent Office has provided no support for this statement. The Patent Office has the initial burden of explaining why the specification is not enabled. (In re Wright 999 F 2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993). Absent a literature reference, the Examiner has not met the burden and this rejection should be withdrawn.

Finally, the Examiner argues that Applicants cannot rely on U.S. 5,942,606, as *prima facie* evidence that Applicants' specification is sufficient to teach those skilled in the art to make and use the claimed invention without undue experimentation.

Applicants cite U.S. Patent No. 5,942,606 as evidence that Applicant's specification does not require undue experimentation having due regard for the nature of the invention and the state of the art.

Firstly, the Patent Office has issued U.S. patent No. 5,942,606 and thus under 35 U.S.C. 262, there is a presumption that the specification is fully enabled.

Secondly, the Patent Office clearly believes U.S. Patent No. 5,942,606 to be fully enabled because it is citing U.S. Patent No. 5,942,606 against the Applicant as 102(e) prior art. The Examiner cites In re Schoenwald (CAFC) 22 USPQ 1671 as support for the premise that an anticipatory reference is not required to disclose a use for a product. Applicants respectfully disagree. More recent case law indicates that "to serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosure cited as prior art is not enabled"" See Elan Pharmaceuticals, Inc. and Athena Neurosciences, Inc. v. Mayo Foundation for Medical Education and Research 2003 U.S. App Lexis 20195 (Fed Cir 2003) citing Amgen, Inc. v. Hoechst Marion Roussel, Inc. 314 F.3d 1313, 1354, 65 USPQ 2d 1385, 1416 (Fed. Cir. 2003).

U.S. Patent No.5,942,606 discloses a protein designated ACVRP, which is identical with the PRO246 polypeptide of the present application, and provides a very similar disclosure to the current specification. It simply provides sequence homology with HCAR as support for the sequence being useful as a viral receptor. The specification of the issued U.S. patent is devoid of any experimental data demonstrating the antiviral activity of ACVRP, or identifying the specific viruses associated with this receptor. Accordingly, if U.S. 5,942,606 is fully enabled, which the Patent Office has determined, then Applicants currently claimed invention is similarly fully enabled. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

CONCLUSION

In conclusion, the present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited. Should the Examiner find that there are any further issues outstanding, she is invited to contact the undersigned attorney at the telephone number shown below.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 08-1641 (Attorney's Docket No. 39780-1618 P2C21).

Respectfully submitted,

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